

REMARKS

By this Amendment, claims 14 and 21 are amended and new claims 30-33 are added. Accordingly, claims 14-33 are pending in this application, claims 15-17 and 23-25 being withdrawn from further consideration. It is respectfully submitted that new claims 30-33 read on the elected species. No new matter is added.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration; (c) satisfy a requirement of form asserted in the previous Office Action; (d) present only allowable additional claims; and (e) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to objection and rejections raised in the final rejection. Entry of the amendments is thus respectfully requested.

Applicants gratefully acknowledge that claims 20, 21, 28 and 29 are indicated as containing allowable subject matter. New claims 30-33 correspond to claims 20, 21, 28 and 29, with claims 30 and 31 corresponding to claims 20 and 21, respectively, rewritten in independent form, including the correction of the typographical error discussed below. Accordingly, Applicants respectfully submits that claims 30-33 are allowable.

Withdrawal of the finality of the rejection is respectfully requested. The Office Action states that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action." Applicants respectfully disagree.

As specifically pointed out in the remarks of the August 25, 2003 Amendment, the language of independent claim 14 differs from original independent claim 1 only to correct formal matters and to reflect an actual commercial embodiment. Although additional features were added, the added features were not necessary to overcome the previous rejection based

on Poirier. Therefore, Applicants' amendments did not necessitate the new ground of rejection.

Furthermore, the previous rejection based on Poirier was fundamentally improper because: (1) the Examiner relied on a foreign language document without providing an English language translation, thus making the record unclear as to the precise facts the Examiner was relying upon in support of the rejection; and (2) the Office Action failed to particularly set forth the basis of the rejection. Therefore, withdrawal of the previous rejection based on Poirier was necessary without the amendments to the claims.

Still further, Applicants specifically pointed out that a feature (the locking means) recited in independent claim 14 which was originally recited in independent claim 1 was not disclosed or taught by Poirier. Because Poirier fails to disclose this originally recited feature, withdrawal of the previous rejection based on Poirier was necessary without the amendments to the claims.

changed the scope

As stated in MPEP §706.07(a), "second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement" (emphasis added). The Office Action clearly sets forth a new ground of rejection, as acknowledged on page 5 of the Office Action. Contrary to the assertion in the Office Action, however, the new ground of rejection was not necessitated by Applicants' amendments to the claims, but was necessitated by the improper rejection based on Poirier in the previous Office Action. Therefore, the finality of the rejection is improper and should be withdrawn.

App amended

Turning to the substance of the Office Action, the drawings are objected to under 37 C.F.R. 1.83(a). As discussed below, the "axial dot" recited in claim 21 is a typographical error and claim 21 is amended to properly recite an "axial slot." An axial slot is shown, for

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example, as slot 41 or 42 in Figs. 12 and 13. Accordingly, withdrawal of the objection to the drawings is respectfully requested.

The disclosure is objected to for the informalities noted in the Office Action. The specification is amended to explicitly state what structure, materials and/or acts perform the function of the claim elements defined by means-plus-function language, as required by the Office Action. Accordingly, withdrawal of the objection to the disclosure is respectfully requested.

Claims 14, 16 and 18-29 are objected to for informalities as noted in the Office Action with respect to the disclosure. In view of the amendments to the specification, withdrawal of this objection is also respectfully requested.

Claims 21 and 29 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. As noted above, claim 21 is amended to correct a typographical error. It is respectfully submitted that claim 21 is not narrowed by such amendment. It is also respectfully submitted that claim 21 fully complies with 35 U.S.C. §112. Accordingly, withdrawal of the rejection of claims 21 and 29 is respectfully requested.

Claims 14, 16, 18, 19, 22, 26 and 27 stand rejected under 35 U.S.C. §102(e) over U.S. Patent Application Publication No. US 2002/0004649 A1 to Jansen et al. (hereinafter, "Jansen"). This rejection is respectfully traversed.

First, Applicants note that the Office Action fails to clearly set forth what features disclosed by Jansen are alleged to correspond to the features recited in the rejected claims. Thus, the Office Action does not sufficiently set forth the factual basis of the rejection. Accordingly, it is respectfully submitted that the rejection is fundamentally improper.

The Office Action refers to Figs. 1-8 of Jansen without identifying a single feature. Although these figures explicitly provide reference numerals that could be utilized by the Office Action, the Office Action fails to even attempt to correlate the features shown in these

figures with the features recited in the rejected claims. Applicants should not have to speculate which features shown in Figs. 1-8 of Jansen are being relied upon to allegedly anticipate the rejected claims. As with the prior rejection over Poirier, Applicants are again left to guess what features disclosed in the figures are being relied upon by the Office Action in support of the rejection.

Accordingly, should it be determined upon reconsideration that the rejection over Jansen is to be maintained, Applicants respectfully request that a new Office Action clearly and explicitly setting forth the factual basis of the rejection be issued. However, as Jansen fails to disclose each and every feature recited in independent claim 14, as discussed below, it is respectfully submitted that the rejection over Jansen should be withdrawn.

Claim 14 recites *inter alia* "a safety assembly for a prefilled syringe . . . comprising a tubular body . . . having a plunger mounted in the body . . . a tubular sheath in which the body of the syringe is designed to be housed in axially displaceable manner . . . resilient return means for urging the body towards its protection position . . . locking means for preventing the body from moving relative to the sheath in the active position by opposing the resilient force of the return means, said locking means being released by release means when the plunger is in its end-of-injection position . . . the release means comprising two diametrically opposite lugs formed in a wall of the tubular sheath, each lug having a free end provided with a retractable catch . . . a cap mounted to slide axially on the sheath between two positions . . . snap-fastening means comprising an internal catch for securing the flange of the tubular body to the cap, so that due to retraction of the retractable catches, the cap is moved by resilient return means; and two complementary shoulders . . ."

Assuming arguendo that element 26 and element 28 shown in Figs. 2-4 and 7 of Jansen are being relied upon by the Examiner to respectively correspond to the cap and the sheath recited in claim 14, it is respectfully submitted that Jansen fails to disclose the release

means recited in claim 14. As noted above, claim 14 recites release means comprising two diametrically opposite lugs formed in a wall of the tubular sheath wherein each lug has a free end provided with a retractable catch. Jansen does not disclose such a release means.

Assuming arguendo that the annular groove 48 on the element 26 and the complementary annular rib 58 on the element 28 are being relied upon by the Examiner to correspond to the release means recited in claim 14, Applicants respectfully disagree. The rib 58 on the element 28 does not comprise two diametrically opposite lugs. Further, the rib 58 does not have a free end provided with a retractable catch.

Further, it is respectfully submitted that Jansen fails to disclose the snap-fastening means recited in claim 14. As noted above, claim 14 recites snap-fastening means comprising an internal catch for securing the flange of the tubular body to the cap, so that due to retraction of the retractable catches, the cap is moved by resilient return means. Jansen does not disclose such a snap-fastening means.

Assuming arguendo that the abutment surfaces 42, 44 on the element 26 are being relied upon by the Examiner to correspond to the snap-fastening means recited in claim 14, Applicants respectfully disagree. As shown in Figs. 4 and 8 of Jansen, and as described, for example, in paragraph [0025] of Jansen, the abutment surfaces 42, 44 are in an opposed spaced relation to each other. The axial spacing between the abutments 42, 44 "corresponds . . . to the axial distance which the syringe can move with respect to the holder."

As such, the abutments 42, 44 are specifically disclosed by Jansen to allow movement between the element 26 and the flange 24 of the syringe body by providing a play between the abutments 42, 44. Because the abutments of Jansen allow relative movement between the flange 24 and the element 26, they do not secure the flange 24 of the syringe body to the element 26. Therefore, the abutments 42, 44 cannot reasonably be considered to be "snap-

fastening means comprising an internal catch for securing the flange of the tubular body to the cap" as recited in claim 14.

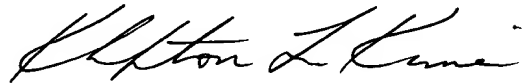
As Jansen fails to disclose at least the release means and the snap-fastening means recited in claim 14, it is respectfully submitted that claim 14 is patentable over Jansen. Further, it is respectfully submitted that claims 16, 18, 19, 22, 26 and 27 are patentable at least in view of the patentability of claim 14 from which they depend, as well as for the additional features they recite. Accordingly, withdrawal of the rejection over Jansen is respectfully requested.

In view of the patentability of claim 14, it is respectfully submitted that the withdrawn claims 15-17 and 23-25 should be rejoined. Rejoinder of these claims is respectfully requested.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 14-33 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:KLK/kzb

Attachment:
Petition for Extension of Time

Date: March 5, 2004

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